Hands-Free Ultrasound Device

By

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Hands-Free Ultrasound Transducer Attachment Report

March 4th, 2019

Team Hands-Free Ultrasound Transducer: Christina Harrison, Harshveer Dhaliwal, & Glenn Farina

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1.0 Executive Summary

This document describes a background on current ultrasound technologies and the troubles that have inspired the need for a hands-free ultrasound transducer device, as well as the regulatory requirements, like patents and standard codes, for the intended invention. It also explains the Stage Gate Review process used to project plan the design of the device, a description of the final design and how it was developed, and the IQ/OQ/PQ. The objectives necessary to design this device, in order to meet all the requirements of the sponsor, are also summarized here. The design process including manufacturing instructions, prototype evolution, and the finalized device are presented. Lastly, project conclusions, recommendations, and acknowledgements are presented in this final report.

2.0 Introduction and Background

Introduction

Ultrasound is a tool that is used to help diagnose and monitor musculoskeletal disorders. Currently options are more limited to manual ultrasound transducers, which require clinicians to hold on to the transducer at the site of imaging. This limits the time the ultrasound can be performed and is labor intensive. With a hands-free adapter, we are able to reduce the involvement of the clinician in the ultrasound process and broaden the use of ultrasound in dynamic settings. Specifically, a hands-free ultrasound would be incredibly useful for ultrasounds performed on the shoulder because the bony anatomy of this area combined with the characteristics of common injuries make this a difficult area to image. This routine diagnostic technique is most often performed in physical therapy establishments.

The most common type of shoulder injury is a rotator cuff tear. This occurs when one or more of the four tendons attaching to the humerus tears, creating shoulder weakness and potentially immense pain (1). The diagnostic procedure for rotator cuff injuries consists of using an ultrasound on the posterior side of the shoulder and moving the arm and/or transducer to locate the site for the image.

There are some options that exist which allow for hands-free imaging. One is a single-use product that utilizes a body adhesive (2), and the other utilizes a band to hold the ultrasound transducer in place (4). Both these options are limited to a non-dynamic settings.

Our project requires us to design a hands-free option for ultrasound that can be used in a dynamic setting in order to better diagnose musculoskeletal disorders in the shoulder. Our design plans on incorporating a cuff and bladder system to maintain a stable pressure on the imaging area, similar to design of a blood pressure cuff. The cuff will have a built in attachment for existing ultrasound devices, specifically the *ButterflyiQ* transducer, to reduce the cost of our product.

Background

Summary of Customer Observations, Meetings, and Interviews

1. 10/10/18: Meeting with Dr. Whitt to discuss general design requirements and acquire contact with a physical therapist.
2. 10/29/18: Facetime meeting with Allison to discuss old projects, her wants and requirements, heat buildup, and our potential ideas.

3. 10/29/18: Meeting with Dr. Whitt and Heylman to discuss potential concept ideas and get direction on what we need to fix for the next presentation.
4. 11/14/18: Facetime call with Allison to discuss final concept idea and ask about any *ButteflyiQ* updates.
5. 11/26/18: Meeting with Dr. Whitt and Heylman to discuss determining the best way to manufacture the device
6. 1/10/19: Meeting with Allison to discuss the flexibility of the device and design requirements.
7. 1/14/19 : Meeting with Dr. Whitt and Heylman to discuss designing the device to be flexible.
8. 2/3/19: Meeting with Dr. Whitt and Heylman to discuss holding the device in place when needed but still having the ability to easily remove it from the adapter.
9. 2/19/19: Meeting with Dr. Whitt and Heylman to discuss validating the testing.
10. 2/25/19 Meeting with Dr. Whitt and Heylman to discuss qualitatively verify our design's ability to perform an ultrasound.

<u>Existing Designs</u>

1. Device: Autosound Hands-Free Ultrasound (2)
    - Producer: Richmar
    - Description: The AutoSound Hands-Free Ultrasound Applicator enables unattended ultrasound therapy treatments, maximizing clinic efficiency while ensuring positive patient outcomes.
    - Design Features:
        - 1 MHz, 3 MHz, and 1 & 3 MHz Sweep Ultrasound Frequency Settings
        - Hands-Free Ultrasound Applicator with Swivel Attachment with 3 Fabrifoam Velcro Straps for Easy Fixation to Any Treatment Area on the Body
        - 4 Individual 3.5 cm² Ultrasound Transducers in Each AutoSound Applicator
        - Sequences Between Each of the Four 3.5 cm² Ultrasound Transducers for 1 Second Each
        - Easily Accessorize the Winner EVO CM2 / CM4 or Therasound EVO Devices for Hands-Free Ultrasound Therapy
        - 1 Year Warranty

    - How our product is different: This ultrasound transducer uses a sticky gel pad to adhere the transducer to the patient, while ours will use a modified blood pressure cuff. Also, this product consists of an entirely new ultrasound device, while ours will be an attachment to existing ultrasound machines.

2. Device: HF54 Hands-Free Ultrasound Therapy Unit with Interferential Muscle Stim and Premod Current (3)
    - Producer: Hill Laboratories Company
    - Description: The HF54 eliminates the two most common application errors (treating for less than ten minutes and treating too large of a surface area)

associated with a traditional manual ultrasound treatment that have been shown to reduce the therapeutic effectiveness of ultrasound.

- Design Features:
    - large (3 5/8") soundhead
    - 3 uniform and harmonized crystals
    - two channels of interferential and premod current for muscle stim
    - $2845

- How our product is different: we will use a traditional sized ultrasound head versus a larger soundhead. Also, this product consists of an entirely new ultrasound device, while ours will be an attachment to existing ultrasound machines.

3. Device: HandsFree Sono (4)

- Producer: BTL
- Description: Creates electronically precise, rotating ultrasound field without necessity of therapist activity. This technology enables very fast, effective and comfortable treatment and reduces operator's fatigue.
- Design features:
    - Equal ultrasound dosage over the entire treated area using Rotary Field Technology (rotating crystals in order to reduce heat-buildup)
    - Alternating frequencies 1 and 3 MHz
    - Two models of the HandsFree Sono: 18 cm^2 with six crystals and 12 cm^2 with four crystals

- How our product is different: The HandsFree Sono device attaches to the patient via velcro strap, while our device will use an attachment method similar to a blood pressure cuff strap.

4. Device: SonoSite X-Porte with HFL38xp transducer (5)

- Producer: Fujifilm
- Description: Ultrasound machine that uses Extreme Definition Imaging to pinpoint precision which dramatically reduces artifact clutter while considerably enhancing contrast resolution. Transducer is for arterial, breast, lung, musculoskeletal, nerve, small parts, and venous imaging.
- Design features: Extreme Definition Imaging Technology (XDI), Intuitive Touchscreen Interface, Simple Infection Control, Real-time Scan-along Learning, Highly Portable
- How our product is different: This device separately utilizes both the ultrasound machine and transducer, while our device will only be applicable to the transducer portion. Also, this device is not hands-free, which is the number one design requirement for our product.

5. Device: Acuson X700 Ultrasound (6)

- Producer: Siemens
- Description: Ultrasound machine used for abdominal, anesthesia, breast, cardiac, gynecology, live 3D / 4D, musculoskeletal, neonatal, OB-GYN, pelvis, prostate, radiology, urology, and vascular ultrasounds. Costs $10,000 - $24,999.
- Design features: SieClear Multi-View Spatial Compounding, Synthetic Aperture Technology (SynAps), 3-Scape™ Real-time 3D Imaging Technology, Tissue harmonic imaging (THI)

- How our product is different: This device separately utilizes both the ultrasound machine and transducer, while our device will only be applicable to the transducer portion. Also, this device is not hands-free, which is the number one design requirement for our product.

Table 2.0.1: Related patents for existing technologies.

Patent Name	Patent Number	Date Granted	Inventor(s)
Hands-free ultrasound probe holder	US6261231B1	9/21/1999, 7/17/2001	David J. Damphousse, Mikhail Kagan
Standoff holder and standoff pad for ultrasound probe	US7029446B2	10/30/2003, 4/18/2006	Martin Edmund Wendelken,Charles Pope
Method and apparatus for hands-free ultrasound	US20100076315A1	9/10/2007, 3/25/2010	Ramon Q. Erkamp, Eric V. Cohen-Solal, Balasundara I. RajuJose M. I. Azevedo
Ultrasonic therapy and assessment apparatus and method	US5458130A	11/8/1993, 10/17/1995	Jonathan J. Kaufman, Alessandro E. Chiabrera

Table 2.0.2: Relevant Technical Literature

Title	Journal	Summary
Comparison of Tissue heating between manual and hands free ultrasound techniques (Gullick).	Physiotherapy Theory and Practice	Manual versus handheld ultrasounds (Rich-Mar AutoSound unit) were used and temperature increase on the skin was recorded. The handheld ultrasounds did not show a significant temperature increase compared to the manual technique.
Analysis of temperature rise and the use of coolants in the dissipation of ultrasonic heat buildup during post removal (Davis).	Journal of Endodontics	It was found that injury due to heat build up can occur within 1 minute of imaging. Use of active coolants and cycles of imaging to reduce risk of injury
Blood Pressure Monitor Fundamentals and Design (NXP)	Freescale Semiconductors	The article lists out the design for a blood pressure monitor cuff and pump.
Design flaw in Walgreen's blood pressure cuff for home measurement (Design Flaw).	Blood Pressure Monitoring	There was a design flaw in a Walgreens blood pressure cuff that caused the cuff to only inflate to half size. The

		seam in the middle of the cuff restricted the air flow to the rest of the cuff.
Overview of Therapeutic Ultrasound Applications and Safety Considerations (Overview of Therapeutic).	J Ultrasound Med	Ultrasounds can be used in a wide variety of applications including imaging and surgical tissue cutting. However, burns can occur if safety guidelines are not followed

Applicable Industry Codes, Standards, and Regulations

1. International Standard ISO 10993 (sections relating to Pyrogenicity, Carcinogenicity, Reproductive and Developmental Toxicity, Degradation Assessments, and Chemical Assessment)
2. International Standard ISO 81060 (sections related to automated cuff and bladder that wrap around the arm)
3. Subject to General Controls

3.0 Customer Requirements and Design Specifications

3.1 IFU

The indicated use for this device is to allow for the attachment of an ultrasound transducer to the shoulder of patients 18 and up, allowing health care providers to perform a “hands-free” ultrasound with the Butterfly iQ transducer or similar sized transducers in clinical settings that perform MSK ultrasound for diagnosis and evaluation.

3.2 Product Design Specifications

Table 3.2.1: Customer Requirements and Design Specifications

Customer Requirement	**Engineering Specification**	**Reasoning**	**Testing**	**Risk**
Easy to Take on and Off	1. 2--5 pound weight maximum 2. Device does not take longer than 2 minutes to put on patient	1. Providers may need to take device off to perform standard ultrasound	1. Weigh device 2. Calculate volume in CAD program	L
Stays on Patient During Movement	1. Displacement of transducer on the skin in the horizontal and vertical direction does not exceed 2 cm after dynamic movement	1. Need for consistent point of contact for imaging	1. Use pressure transducer to measure force 2. Research material friction coefficients	M
Comfortable for Patient	1. Biocompatible (non--irritating) 2. Pressure of cuff does not exceed 150 mm Hg	1. Skin-to-device contact should not cause a reaction/irritation 2. Must be comfortable for patient in motion	1. <1% of patients statistically not allergic to chosen material 2. Use pressure transducer to measure force	H

Hands Free	1. Device does not require operator 2. Transducer stays in device with up to 10 N of pulling force in the normal direction away from device	1. Premise of design	1. Test device to make sure there are no failures that will result in need of an operator	H
Reasonably priced	1. Parts and labor do not exceed more than $500	1.Care facility must be able to afford it	1. Use excel to estimate costs	M

3.3 House of Quality

Table 3.3.1: House of Quality rooms 1, 2, 4, & 5

		Engineering Characteristics				
Improvement Direction		Down	Down	N/A	Up	Up
Units		Lb	cm^3	Pa	None	% Similar
Customer Requirement	**Importance Weight Factor**	Weight	Volume	Pressure Exerted on Patient	Static Friction Coefficient on Skin	Precision of Images
Easy to Take on and Off	3		3			
Stays on Patient During Movement	4			8	9	7
Still Produces Accurate Images	4			5	5	9
Comfortable for Patient	4	9	8	8	6	
No Increase in Heat Buildup	5					
Hands Free	5	7	7	6	4	
Reasonably priced	3					6

Able to Be Used Multiple Times	2					
Raw score (792)		71	76	114	100	82
Relative Weight (%)		8.96%	9.6%	14.39%	12.63%	10.35%
Rank Order		7	6	1	4	5

		Engineering Characteristics				
Improvement Direction		Down	Down	Down	Down	Up
Units		% of Patients Allergic	Degrees Fahrenheit	Percentage	US Dollars	Cycles
Customer Requirement	**Importance Weight Factor**	Percentage of Patients Allergic to Material	Temperature of Probe	Percent Device Requires Operator to Interfere	Price	Cycles Until Failure
Easy to Take on and Off	3					
Stays on Patient During Movement	4			7		
Still Produces Accurate Images	4		8		6	9
Comfortable for Patient	4	9	7			
No Increase in Heat Buildup	5		9	6		
Hands Free	5			9		
Reasonably priced	3				9	
Able to Be Used Multiple Times	2					9
Raw score (792)		36	105	103	51	54
Relative Weight (%)		4.55%	13.26%	13.01%	6.44%	6.82%
Rank Order		10	2	3	9	8

Table 3.3.2: House of Quality Room 6.

Room 6: Customer Assessment of Competing Products		
Competitor Rankings: 1–Poor, 3–OK, 5–Excellent		
Richmar	Hill Laboratories Company	BTL
4	3	4
3	3	1
4	4	4
4	2	4
4	4	4
5	5	5
3	3	3
4	5	5

4.0 Stage Gate Process

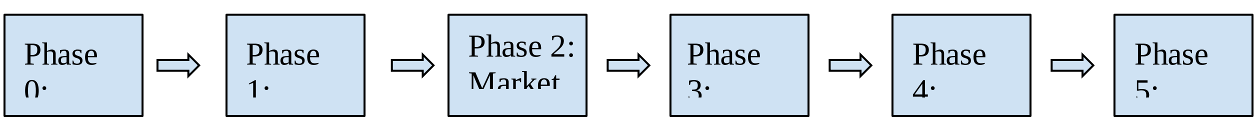


Figure 4.0.1: Stage Gate Process-The 5 stages of the Stage Gate Process

4.1 Concept Review

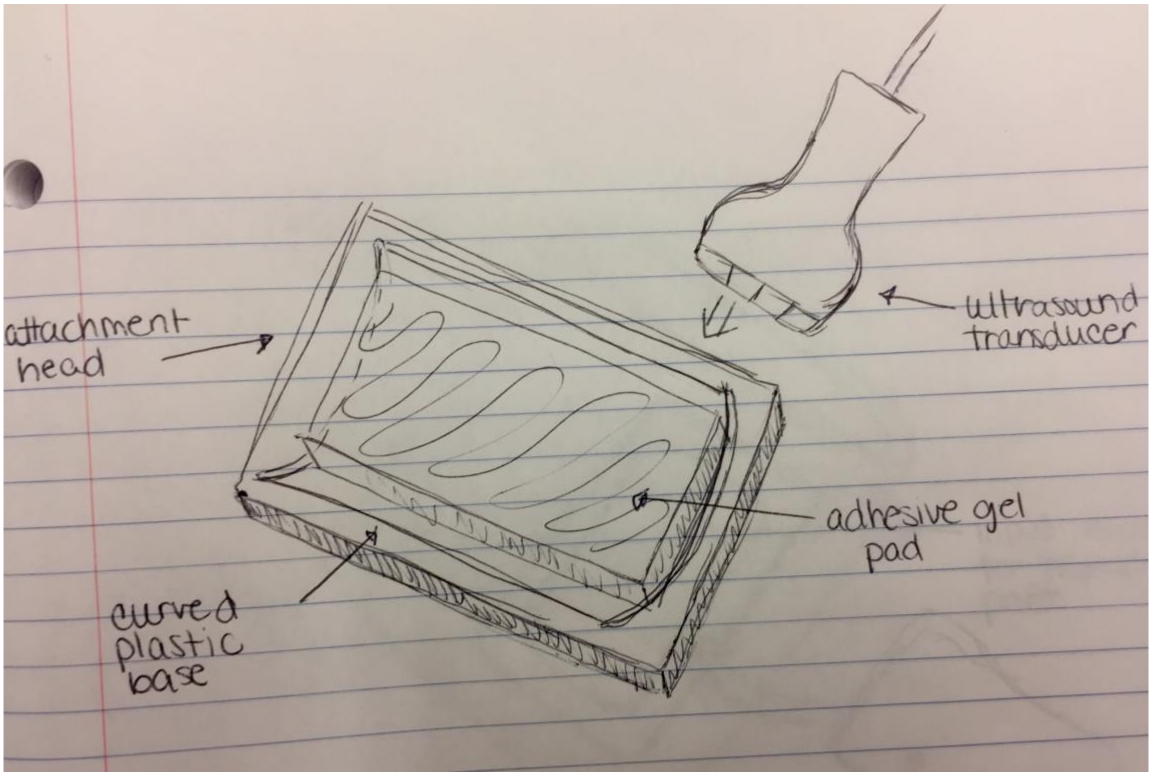


Figure 4.1.1: Concept 1–Description and Justification: The gel adhesive pad is placed on the patient and the transducer probe pulses to produce an image. This would work well, but the use of conductive gel will make the pad less adhesive. Also, this device will not be easily adjustable, which is a necessity in order to achieve the best ultrasound image.

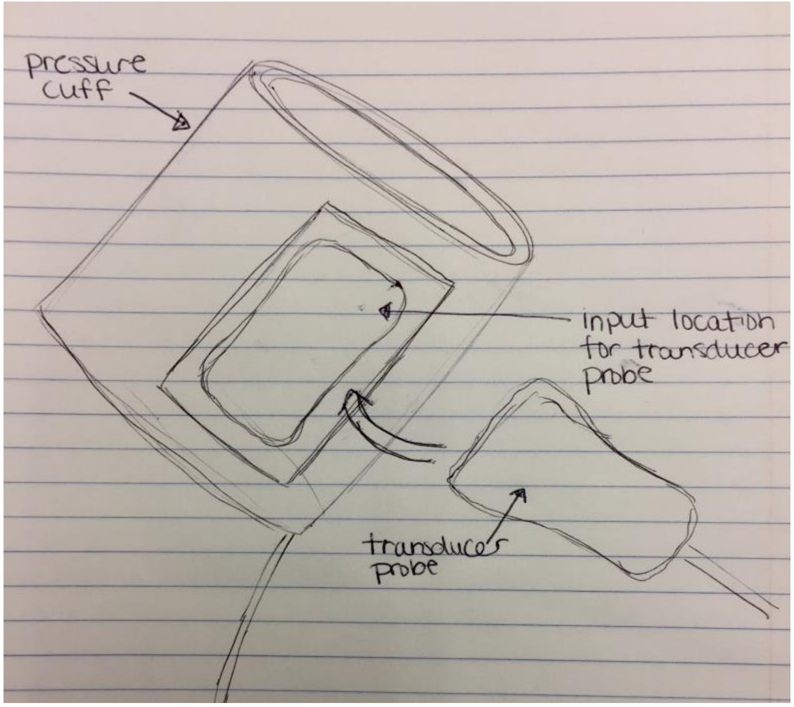


Figure 4.1.2: Concept 2–Description and Justification: This design consists of a blood-pressure type cuff, allowing for a flexible adapter for the ultrasound while keeping the device stable on the imaging area. However, this device is not compatible with the shoulder.

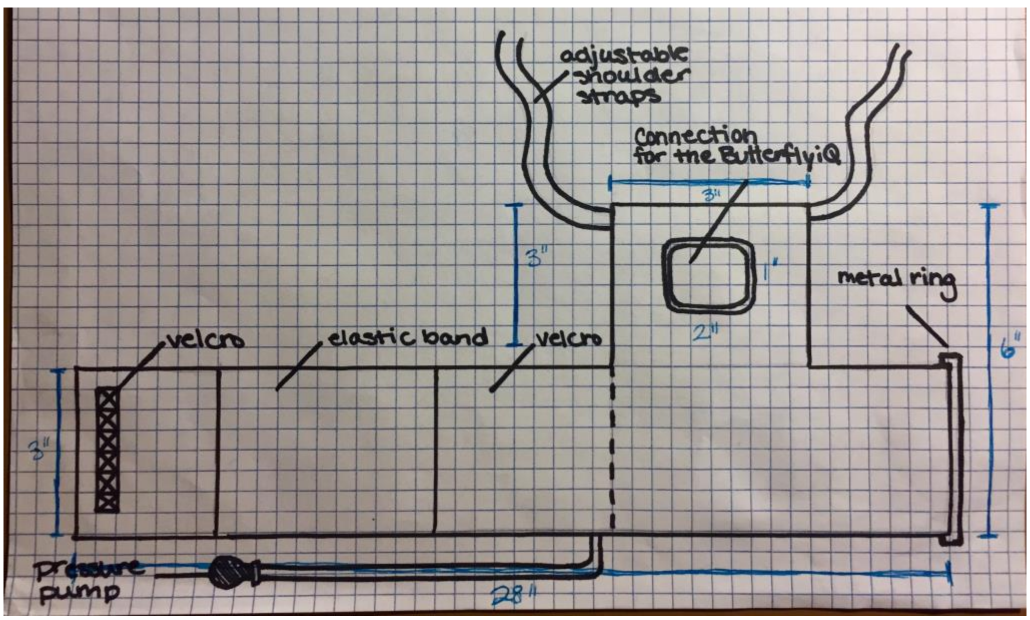


Figure 4.1.3: Concept 3–Description and Justification: Arm cuff with an extension that allows for the transducer to attach on shoulder area (similar to Concept 2). Adjustable shoulder straps wrap around the body and are used to hold the cuff extension in place on the shoulder.

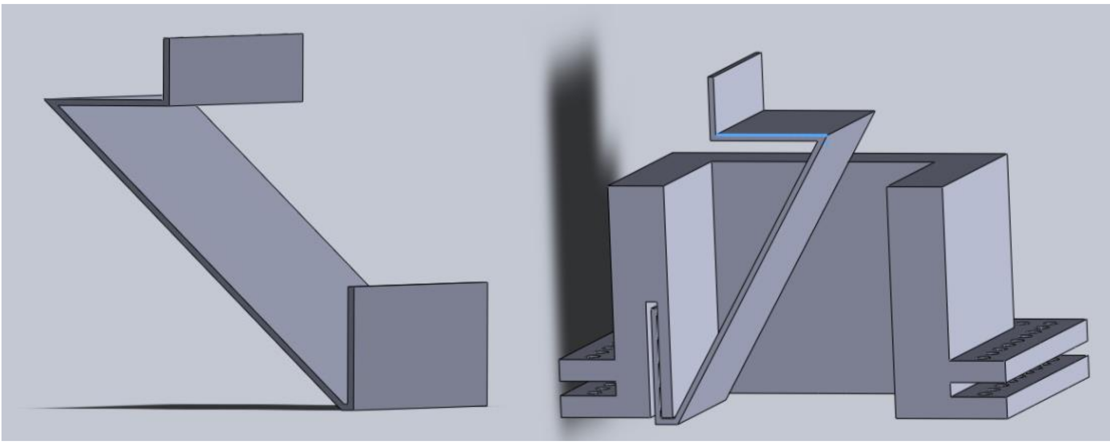


Figure 4.1.4: Detail of Concept 3–SolidWorks models of the metal clip (left image) and how it will fit into the attachment ring (right image). This will be stitched into the cuff extension in order to hold the transducer in place.

4.2 Design Freeze

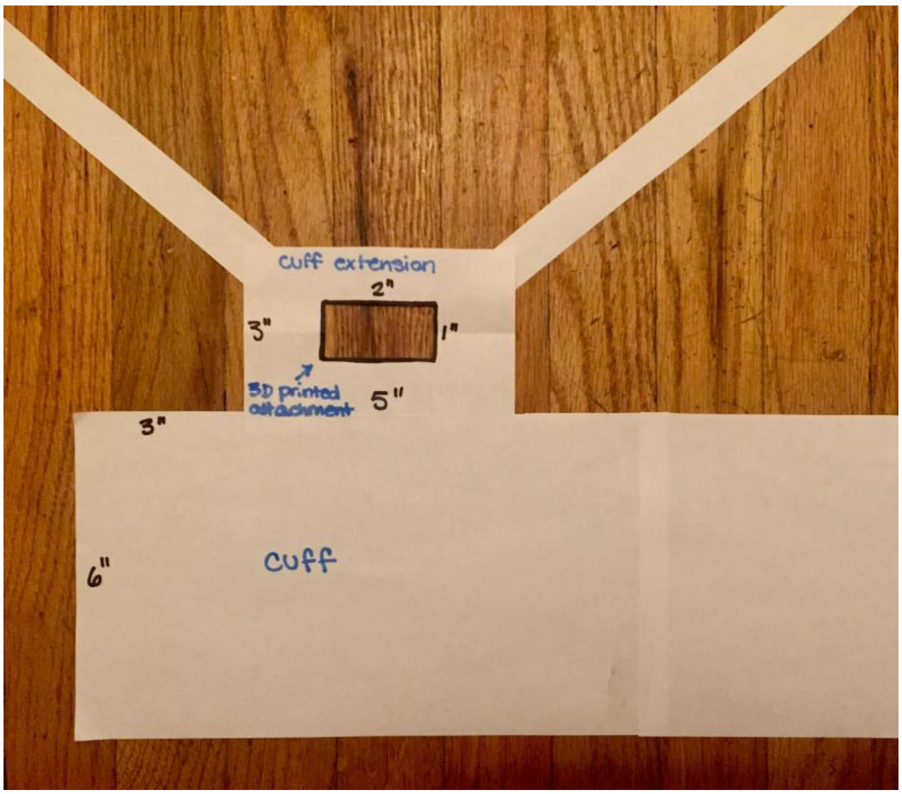


Figure 4.2.1: Dimensioned Model–Dimensioned Paper Model of Device

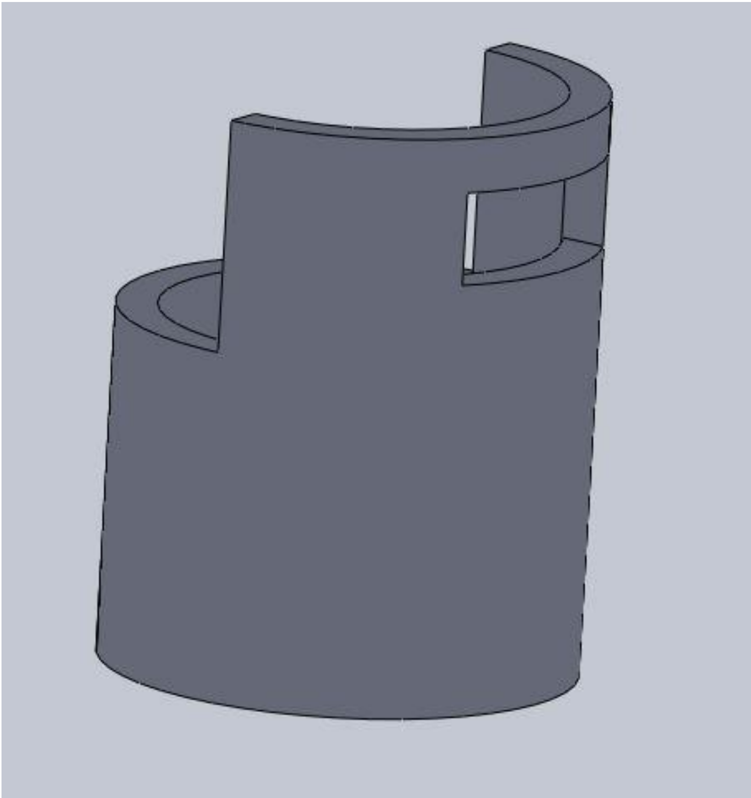


Figure 4.2.2: CAD Model Of Cuff–Screenshot of cuff in Solidworks

Figure 4.2.3: Device Demonstrated on Patient–Paper model of device attached to a patient

Figure 4.2.4: Profile View of Device Demonstrated on Patient–Profile view of paper model of device attached to a patient

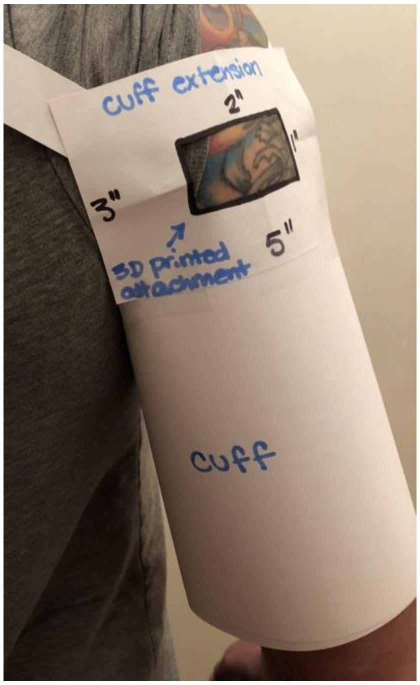


Figure 4.2.5: Posterior View of Device Demonstrated on Patient–Posterior view of paper model of device attached to a patient

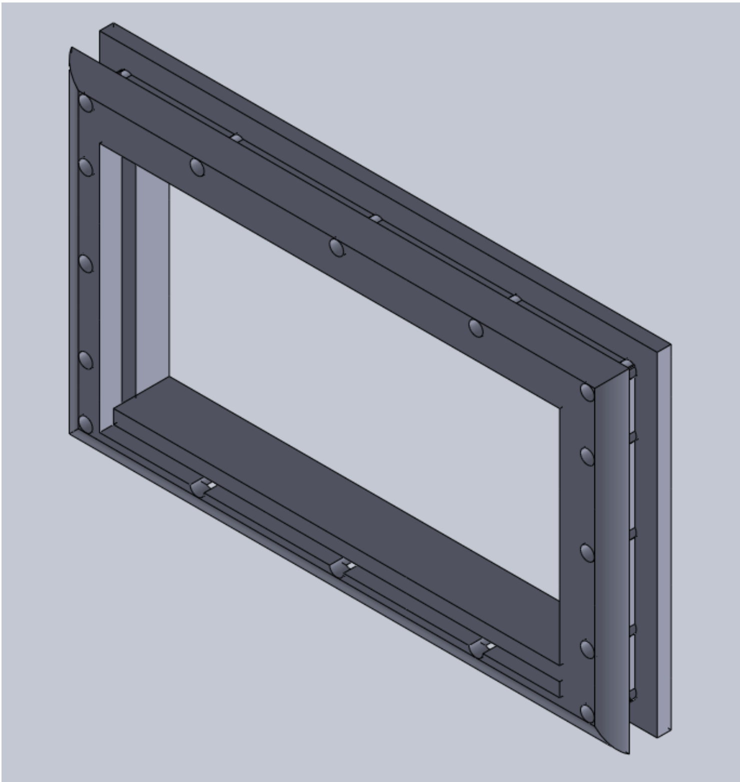


Figure 4.2.6: CAD Model of Attachment Ring–Screenshot of attachment ring in Solidworks

Figure 4.2.7: Clip Model–Model of clip that will be used to secure transducer to device

4.3 Design Review

After reviewing the three design concepts, Concept 3 was selected. With the flexibility of the attachment point, this design meets the required position specifications while remaining flexible enough to stay placed on the patient during arm motion. The clip secures the transducer in place without altering the transducer. Concept 1 was not selected because the conductive gel used during an ultrasound will alter the adhesive properties of the device, resulting in greater chance of displacement. Concept 2 was not selected because without the cuff extension, the device is not compatible with the shoulder.

5.0 Description of Final Prototype Design

5.1 Overview

The design from Concept 3 was modified in order to create the final prototype. Alterations based on testing and sponsor specifications were made, like adding another window for a second transducer and more straps to hold the device securely in place (see **Figure 6.2.3**).

5.2 Design Justification

In order to allow for multiple anatomical regions to be evaluated, a second attachment window was added in the vertical direction, creating both horizontal and vertical windows. Because this was a large amount of surface area added to the cuff extension, the corners at the base of the cuff extension were cut out, making the cuff extension width 3 inches instead of 8 inches. This allows the device to fit around patient's shoulders more snugly, especially those with small arms and shoulders. Velcro was chosen as the main attachment mechanism for holding the transducer in place because of its easability to add to almost any surface and it is more secure than the metal clip method. The cross-body straps and cords were added to the cuff extension in the middle of each attachment window in order to hold each window as close to the skin as possible during dynamic movements. The bottom of the device that is in contact with the shoulder was painted with liquid electrical tape so that the neoprene would not absorb the conductive gel used during the ultrasound as well as to ease the cleaning process. Neoprene was chosen as the base material for the device because of its thick but elastic properties, creating stability while still being comfortable on the patient's skin. Lastly, a blood pressure cuff was utilized because it allows for the device to fit over any arm size by tightening the wrap using velcro and/or pumping the cuff with air.

5.3 Analysis

The final device consists of a blood pressure cuff attached to a neoprene cuff extension that contains two attachments sites where the ultrasound transducer can insert and be held in place via velcro. One attachment site is horizontal and the other is vertical so the physician can orient the transducer in either direction in order to increase the amount of tissue possibilities available during examination. The device comes with a velcro belt that snuggly fits around the transducer, then the corresponding velcro pieces are on the attachment windows of the device. A physician can put the device on a patient by wrapping the cuff around the lower portion of the upper arm and securing it snugly via. The cuff can be pumped with air using the pressure balloon in order to comfortably hold the device in place. The device can be rotated on the arm so that either attachment window lines up with the anatomical region being analyzed. Next, the physician will secure the cuff extension portion of the device by wrapping the thin neoprene straps across the patient's chest and securing them under the opposite armpit via velcro. The cord portion on the top of the cuff extension is then pulled over the shoulder and the velcro strap. To keep the attachment windows in contact with the skin. Lastly, the velcro belt is slipped onto the transducer and inserted into the attachment window being used and the ultrasound is performed.

5.4 Cost Breakdown

Table 5.4.1: Bill of Materials

Material/Quantity	**Supplier**	**Cost**
Sphygmomanometer (2)	Amazon	$20
Velcro Packet (3)	Ace Hardware	$10

Wetsuit Neoprene 12x12 in (1)	Fetsy	$13
Liquid Electrical Tape (1)	Ace Hardware	$4
Industrial Thread Spool (1)	Beverly’s	$5
Industrial Sewing Needle Pack (1)	Beverly’s	$9
Plastic Epoxy (1)	Ace Hardware	$6
File (1)	Ace Hardware	$5
Protractor (1)	Ace Hardware	$5
Wire (1)	Ace Hardware	$2
Elastic Cord 54 inches (1)	Ace Hardware	$3
Ring for attaching cord (1)	Ace Hardware	$1
Total Cost	**$83**	

5.5 Safety Considerations

Potential Risks and Hazards

While either designing this device or while the device is being used, hazards include prolonged exposure to ultrasound waves, over-tightening of cuff, and irritation of previously damaged body parts (specifically the shoulder) (see Appendix D). These could cause overall patient discomfort along with potential tissue or limb damage. We plan to mitigate these risks by using large volumes of conductive gel during ultrasound procedures and testing, not leaving the transducer in one location on the skin for more than 10 minutes, and by repeatedly asking the patient if they are experiencing pain and discomfort. We could also experience a potential hazard in the machine shops while designing the device, so to mitigate this we will comply with all shop rules and regulations.

Plans for Decreasing Risks and Hazards

1. Use large volumes of conductive gel (>22 ml/procedure)
2. Ultrasound does not exceed 10 minutes in one place on skin
3. Listen to patient; ask if they are in pain/discomfort
4. Ask if the patient is experiencing any shoulder pain/discomfort before the device is put on and adjust the pressure of the cuff accordingly

6.0 Prototype Development

6.1 Model Analyses

In the first prototype, we had a neoprene attachment connected to a blood pressure cuff and used velcro straps to secure the device to the patient. There was one attachment ring in the neoprene extension where the transducer could be placed. In the next prototype another attachment ring was added to allow ultrasounds to be performed on different regions of the shoulder. In the final manufactured prototype a bungee cord was added for extra security.

6.2 Evolution of Prototypes

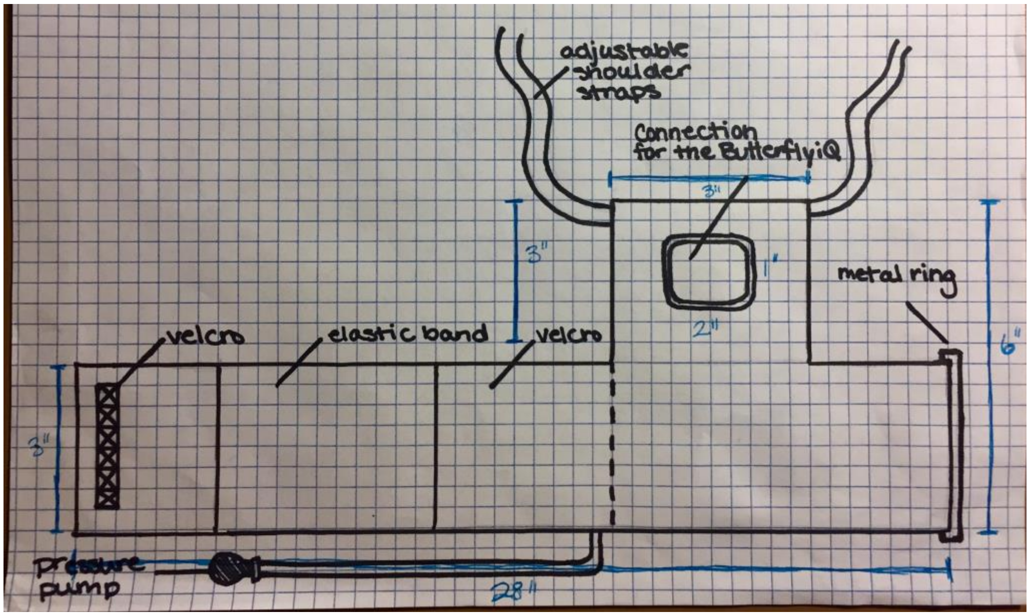


Figure 6.2.1: Prototype Presented in Design Freeze-Initial prototype had only one attachment ring

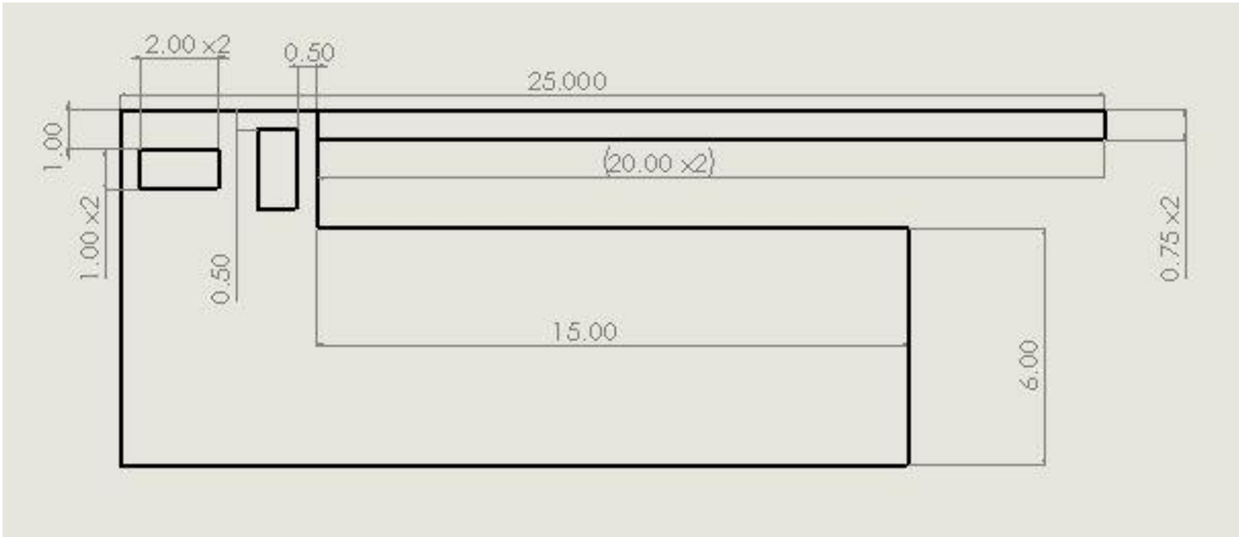


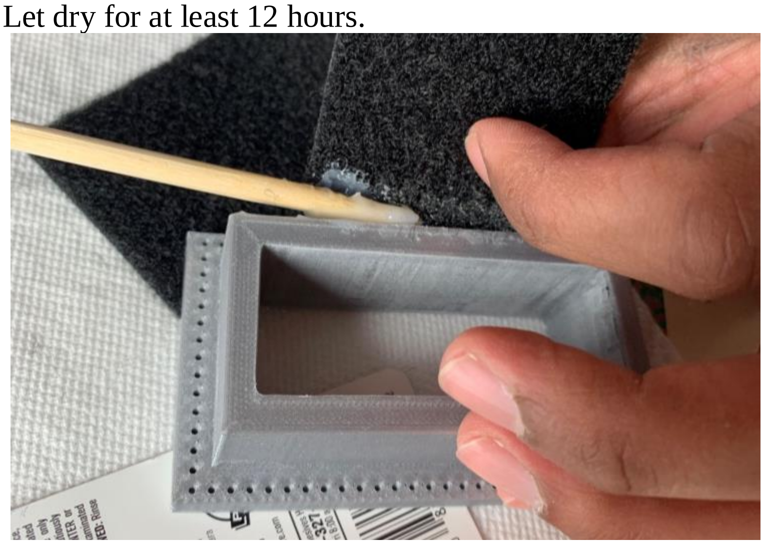
Figure 6.2.2: Prototype Presented in Final Prototype Presentation–A second attachment ring was added to the design in order to allow ultrasounds to be performed on different areas of the shoulder.

Figure 6.2.3: Manufactured Prototype–Velcro straps were moved to the sides of the extension and a bungee cord was added for extra security.

6.3 Manufacturing Process

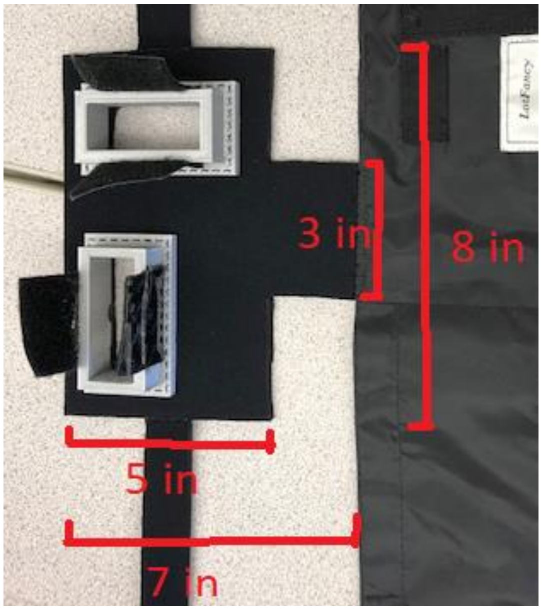
1. 3D print two transducer attachments using PLA.
    a. 3D printing specifications: Infill Pattern: Triangles, Infill Line Distance: 6.3mm, Infill Layer Thickness: 0.2mm, Printing Temperature: 205℃, Retraction Distance: 6.5mm, Retraction Speed: 25mm/s, Print Speed: 70mm/s)

2. Attach two 2x2 inch strips of loop velcro to the long sides of the 3D printed attachment ring using plastic epoxy adhesive. Repeat for second 3D printed ring (see image below). Let dry for at least 12 hours.

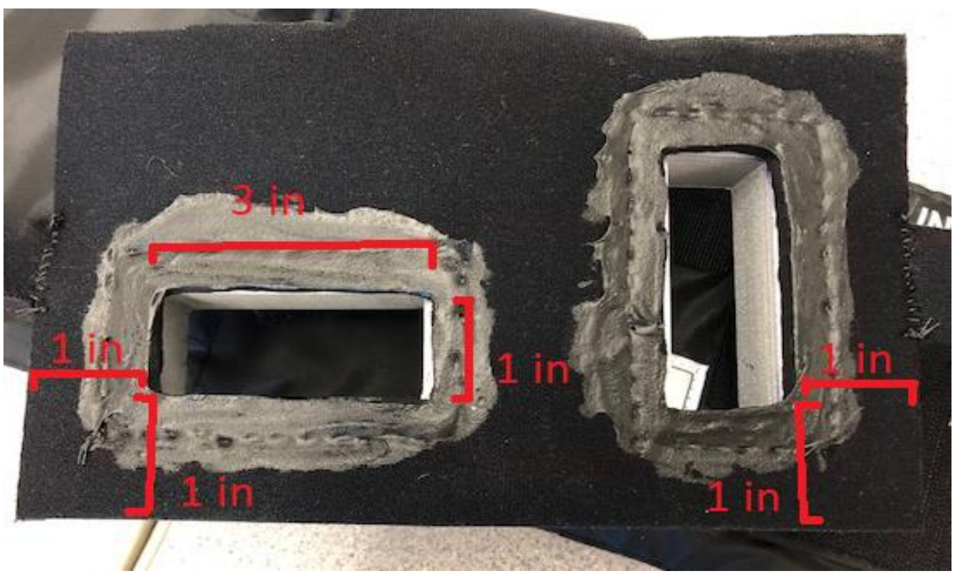


3. On the previously purchased blood pressure cuff, using a Sharpie, make a mark 10 inches from top left corner of the cuff. Set cuff aside until later.

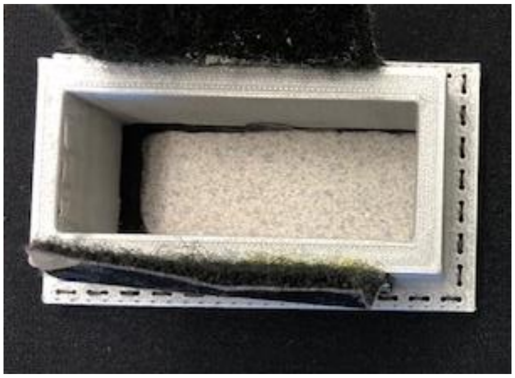
4. On the neoprene sheet of fabric, mark and cut an 8x7 inch rectangle to create the cuff extension.

5. To make the cuff extension fit to the shoulder, cut the 8x7 inch strip as follows:


6. Cut two 1x3 inch rectangles in the center of the neoprene extension for the transducer attachment. Make one horizontal and one vertical.



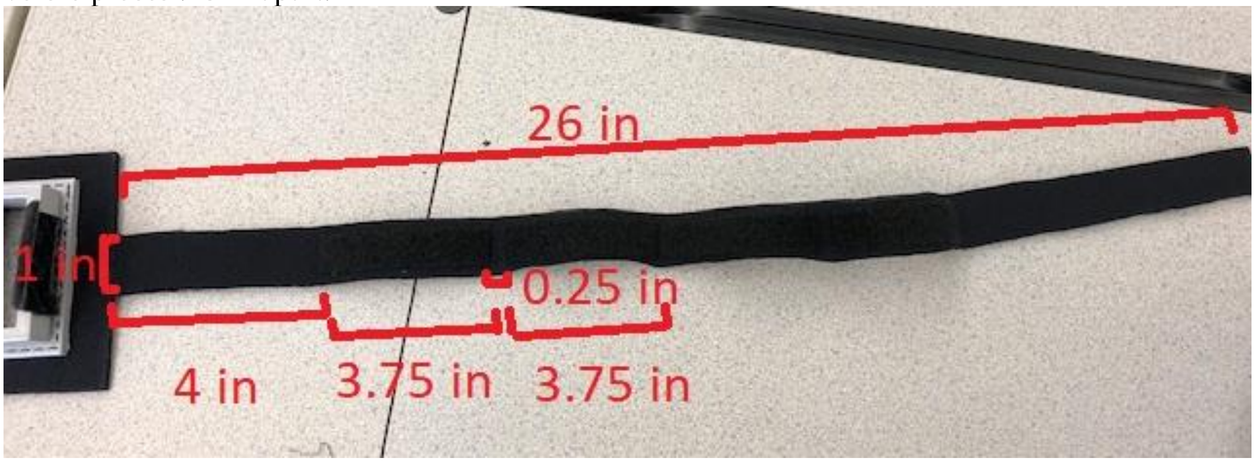
7. Place 3D printed rings onto rectangular holes on neoprene and stitch through the holes of the ring into the neoprene using industrial thread to secure the ring.



8. Using industrial thread, sew neoprene extension onto the existing cuff, aligning the edge of the protruding section of the extension with the previously marked spot on the cuff.

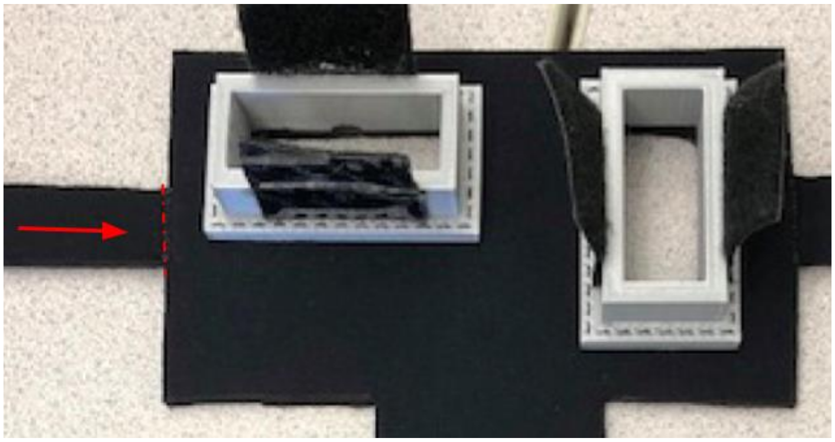
9. Cut two thin, long strips of neoprene (1x26 in each) to make the cross-body straps.

10. Sew 4 loop velcro pieces (1x3.75 in each) onto the end of one neoprene strip, spacing the velcro pieces .25 in apart.

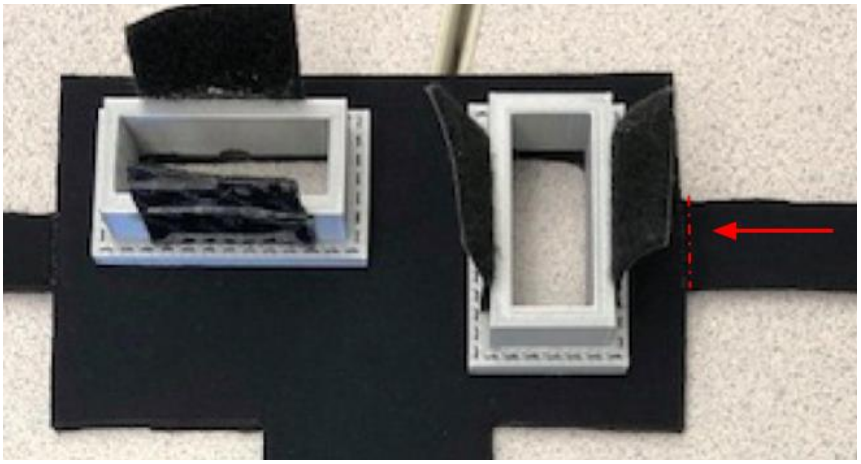


11. Sew 4 hook velcro pieces (1x3.75 in each) onto the end of the other neoprene strip, spacing the velcro pieces .25 in apart.

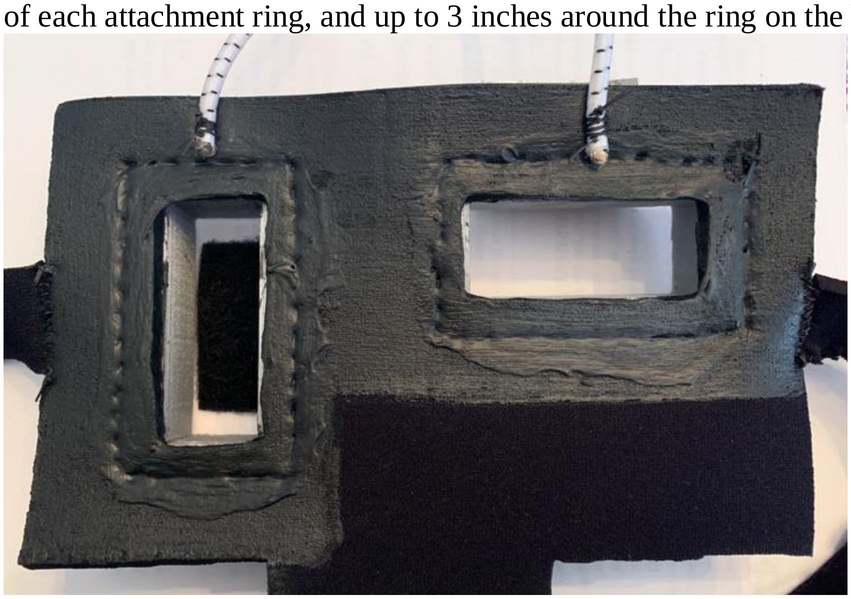
12. Sew the first neoprene strap with the loop velcro to the center of the side of the cuff attachment containing the vertical transducer attachment.



13. Sew the second neoprene strap with the hook velcro to the center of the side of the cuff attachment containing the horizontal transducer attachment.



14. Flip device upside down and spread a thick layer of liquid electrical tape onto the inside of each attachment ring, and up to 3 inches around the ring on the back side of the cuff.



15. To make transducer belt, cut a 1x7 in piece of neoprene and sew short ends together, making ring.

16. Stitch two 1x2 inches pieces of hook velcro on front and back of neoprene ring, spacing each piece 1.5 inches apart.

17. Cut a 12 inch piece of cord and slip the small plastic ring on the cord. Sew each end of cord onto the bottom side of the top of the cuff extension, lining each side of the cord up with the center of the corresponding attachment window

18. Cut another 42 inch long piece of cord and loop it through the small plastic ring. Tie the hook into the two loose ends of the cord.

19. Stitch hook velcro onto bungee strap.

6.4 Divergence Between Final Design and Final Functional Prototype

Table 6.4.1: Design History Record–Documented deviations in the manufacturing and designing process as they were completed.

MPI Step(s)	Deviations from MPI	Completed By	Date
1(V1)	Had to sand down 3D printed transducer to account for tolerances	Harsh	2/2/19
2-6 (V1)	Replaced metal clip with velcro	Harsh	2/6/19
8 (V1)	Changed dimension of neoprene rectangle to 8x7 in	Glenn	2/8/19
9 (V1)	Changed rectangle cuts to 1x3 in	Harsh	2/8/19
11 (V1)	Put epoxy on velcro instead of metal clip	Glenn	2/8/19

13 (V1)	Changed dimensions of neoprene strips to 1x26 in for each	Christina	2/8/19
14 (V1)	Changed sewing location of neoprene straps to middle of cuff	Christina	2/8/19
16-21 (V1)	Removed sewing steps. Assume manufacturer knows how to hand sew	Glenn	2/9/19
15 (V2)	Added sock attachment to transducer	Christina	2/9/19
Added Steps 17-19 (V2)	Added extra strap	Christina	3/2/19

7.0 IQ/OQ

Installation Qualification

Table 7.0.1: Materials Used and How

Material	Description of how material was used
Sphygmomanometer	Used as the cuff portion of the device
3D printed	Used to make the model transducer and the attachment rings
Velcro Packet	Corresponding velcro strips were used on the attachment rings, the transducer belt, and the crossbody neoprene straps
Wetsuit Neoprene 12x12 in	Neoprene was used to make the cuff extension, the transducer belt, and the crossbody straps
Liquid Electrical Tape	This was painted on the bottom side of the cuff extension surrounding the attachment windows
Industrial Thread Spool	All sewing was performed using this: attaching the 3D printed rings to the cuff extension, attaching the cuff to the cuff extension, attaching the neoprene straps and the cord to the cuff extension, making the neoprene

	transducer belt, and attaching all velcro to the neoprene straps
Industrial Sewing Needle Pack	All sewing was performed using this: attaching the 3D printed rings to the cuff extension, attaching the cuff to the cuff extension, attaching the neoprene straps and the cord to the cuff extension, making the neoprene transducer belt, and attaching all velcro to the neoprene straps
Plastic Epoxy	Used to glue the velcro pieces to the 3D printed attachment rings
File	Used to file 3D printed parts to decrease tolerance
Protractor	Used to measure angle of deflection of transducer during structural testing
Wire	Used to attach the model transducer to the grips of the Instron machine during pull testing
Elastic Cord 54 inches	Used as the securing straps on the top of the cuff extension
Plastic Ring	Connects the two pieces of cord on the top of the cuff extension
Scissors	Used to cut all neoprene, velcro, thread, and cord
Sharpie Pen	Used to make marks for dimensioning and cutting raw materials
Measuring Tape	Used to make all measurements on each raw component of the device
Sand	Used to fill model transducer to make it the same weight as the *ButterflyiQ*
Crayola Markers	Used to draw rectangles on test subject's skin in the transducer window for displacement testing

Operation Qualification

Table 7.0.2: Customer requirements translated into engineering specifications and how each were achieved.

Customer Requirement	**Engineering Specification**	**Justification of how the engineering requirements have been met**
Easy to Take on and Off	1. 2--5 pound weight maximum 2. Device does not take longer than 2 minutes to put on patient	1. Weight was measured to be 1 pound using a standard scale, which is less than the cutoff 2. Three different subjects put the device on a test subject and the process was timed. This was repeated 5 times each. The average time for device fitting was 80 seconds.
Stays on Patient During Movement	1. Displacement of transducer on the skin in the horizontal and vertical direction does not exceed 2 cm after dynamic movement	The device was put on the patient and a rectangle in the transducer window was traced. The model transducer was put in the device and dynamic movements were performed. The transducer was removed and a second rectangle was traced in the transducer window. Displacement between each traced rectangle was measured in the horizontal and vertical directions. This process was repeated for each transducer window on differing shoulders in different locations (see section **7.1.3**).

Comfortable for Patient	1. Biocompatible (non--irritating) 2. Pressure of cuff does not exceed 150 mm Hg	All materials used are biocompatible and the three subjects deemed the device comfortable. The cuff does not need to be pumped to a pressure higher than 20-30 mmHg to stay in place.
Hands Free	1. Device does not require operator 2. Transducer stays in device with up to 10 N of pulling force in the normal direction away from device	1. After the initial setup of the adapter on the subject, all dynamic tests were performed without any intervention. 2. A pull-test was performed by attaching a wire to the model transducer and to the grips of an Instron machine. The Instron machine was turned on and ran until displacement occurred between the model transducer and the attachment window. This test was repeated 10 times and the maximum force before displacement was recorded, averaging to be 44 N (see section **7.1.2**).
Reasonably priced	1. Parts and labor do not exceed more than $500	The total cost to fabricate this device was $83 (see **Table 5.4.1**)

For detailed testing protocol showing how each engineering metric was met and tested, see sections **7.1.1-7.1.3.**

Table 7.0.3: Testing Summary Table

Engineering Metric	**Test Results**
2--5 lb weight maximum	Total weight 1lb
Device does not take longer than 120 seconds to put on patient	Average fitment of 80 seconds
Displacement of transducer on the skin in the horizontal and vertical direction does not exceed 2 cm after dynamic movement	Displacement of 0.83 ± 0.575 over 24 trials
Pressure of cuff does not exceed 150 mm Hg	During movement, pressure does not exceed 120 mm Hg
Transducer stays in device with up to 10 N of pulling force in the normal direction away from device	Average pullout force of 44.08 N

Table 7.0.3 presents the data obtained from the varying tests performed to meet the specific engineering metrics designed to meet the device requirements. The weight of the completed prototype was 1 pound less than the maximum range, showing that this metric was

more than achieved. Because the cuff only requires 20-30 mmHg to stay on the arm and only exhibits about 120 mmHg when the subject flexes their arm, the metric of not reaching 150 mmHg was also accomplished. These design specifications mitigate the high risk of patient discomfort, making them very important characteristics. The average pull-out force required to pull the model transducer from the device was about 44.08 N, well above the minimum requirement of 10 N. During dynamic testing, the displacement of the transducer being on average 0.83 cm instead of 2 cm proves that the device will stay in contact with the anatomical region being analyzed. These two factors show that the device will successfully stay in place, mitigating the risk of inaccurate ultrasound readings.

7.1 DOE

7.1.1 Initial Structural Testing

Place 3D printed model transducer in prototype and hold prototype in different positions

a. Prototype is on flat surface, transducer is upright and perpendicular to device.
b. Prototype held vertically in air, transducer is horizontal facing out right, still perpendicular to device.
c. Prototype held vertically in air, transducer is horizontal facing out left, still perpendicular to device.
d. Prototype held horizontally upside down in air, transducer is vertical and facing towards the ground.

Measure the angle of the transducer relative to the attachment for each case described above.

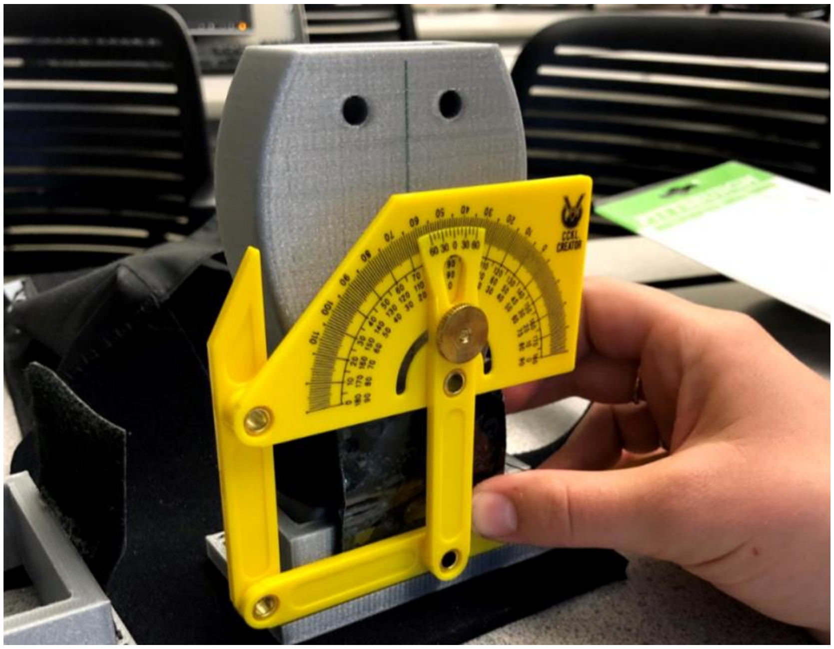


Figure 7.1.1.1: Initial Structural Testing Set Up–Deflection of the model transducer was measured with protractor

7.1.2 Instron Testing

1. Attach metal wire through holes in 3D printed model transducer.
2. Attach other end of metal wire to Instron clamp.
3. Run Instron until model transducer is pulled out of the prototype. Record force at which this occurs.
4. Export data into Excel.
5. Repeat the process 10 more times.
6. Combine data and analyze peak pulling force the moment before the model transducer is pulled out of the prototype.
7. Compare maximum force with statistical goal force.

Repeat this process using the same transducer in the second attachment hole.

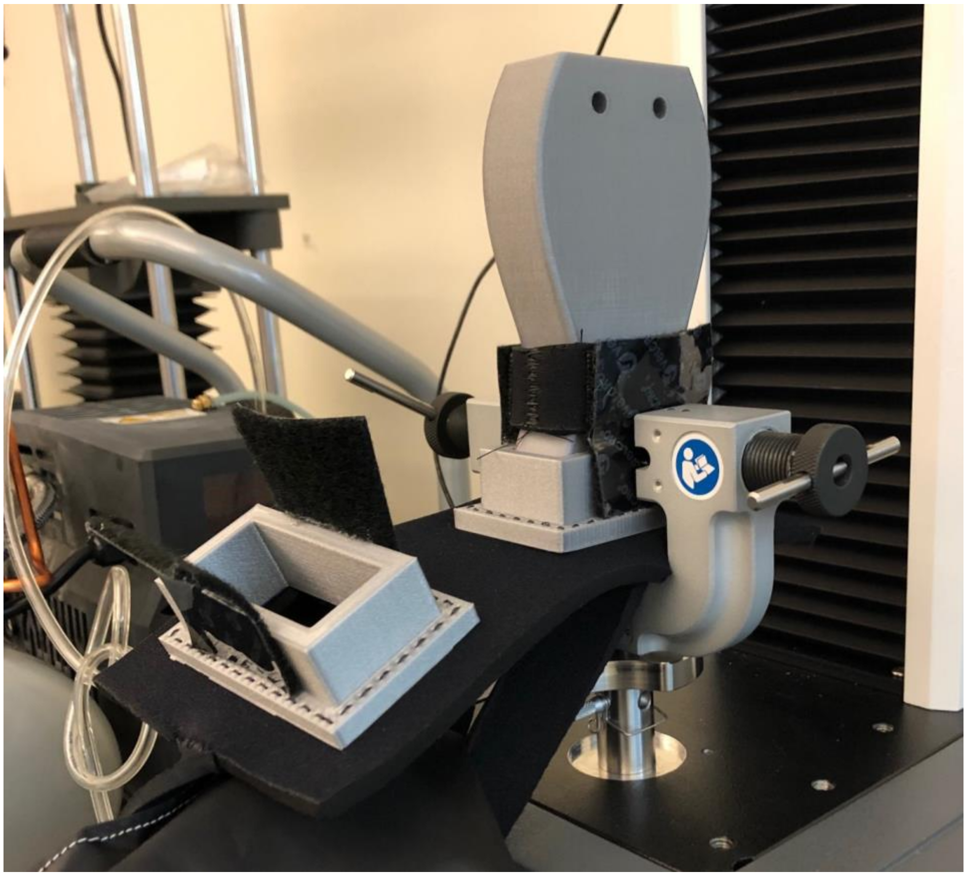


Figure 7.1.2.1: Instron Initial Setup–How the model transducer was clamped into Instron

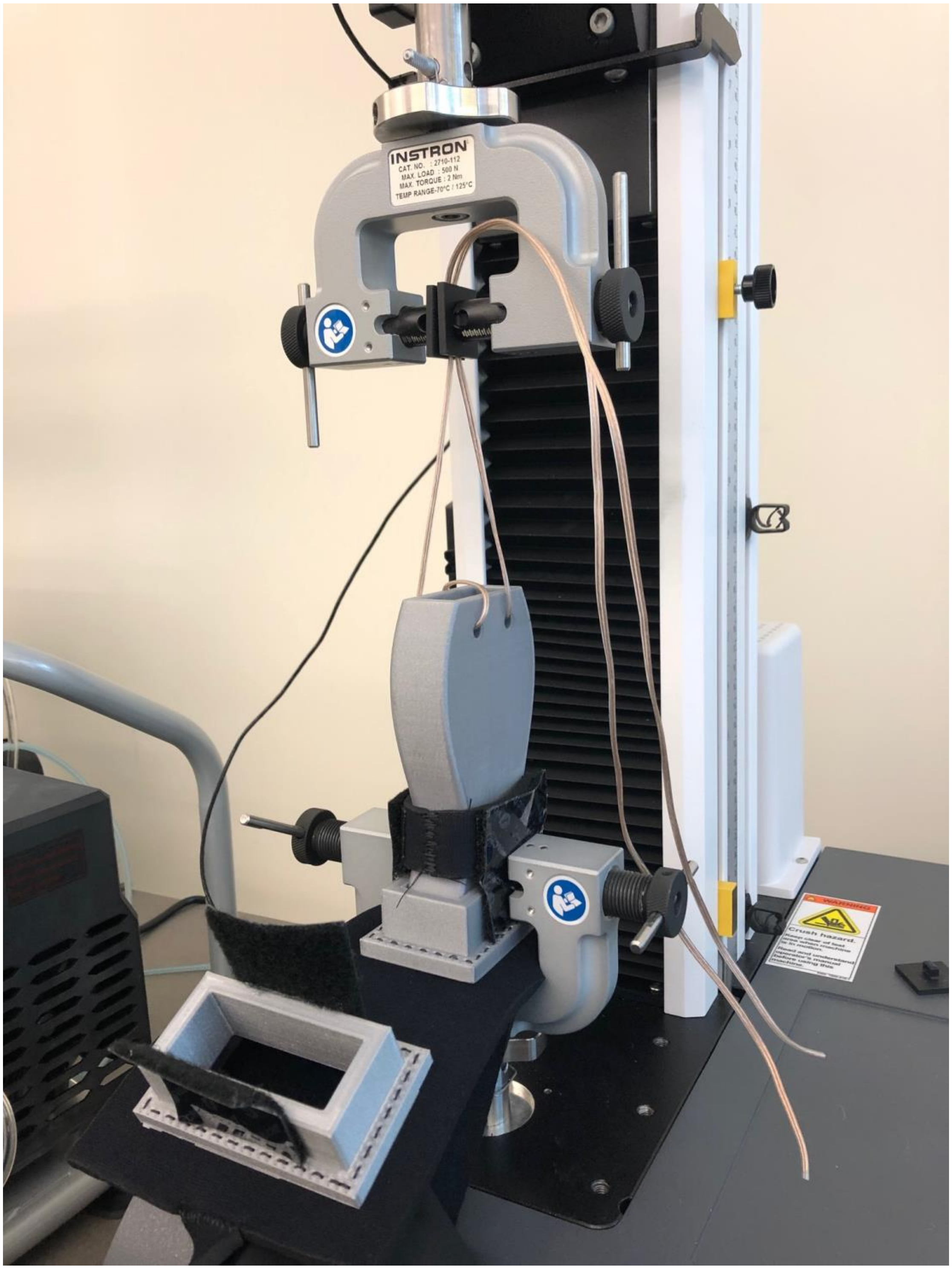


Figure 7.1.2.2: Instron Chord Setup–How the model transducer was connected to the chord

7.1.3 Dynamic Movement Human Movement Testing

1. Place device on test subjects (3) dominant arms. Pump cuff with air until it reaches about 20 mm Hg. Using washable markers, create a outline of slot on skin.
2. Place 3D printed model transducer into attachment hole and perform a series of dynamic movements:
    a. Extend arm up and forward until a 90º angle is made with respect to the body.
    b. Extend arm up and backward until a 90º angle is made with respect to the body.
    c. Extend arm out and upward until a 90º angle is made with respect to the body, making sure the arm is in line with the shoulder and chest.
    d. Extend arm out from side at 45º, then make circles in the forward direction the size of basketball (like tracing a basketball in the air with your hand).

3. Measure angle of deflection of transducer relative to attachment. Create outline of slot on skin after test. Measure horizontal and vertical distance traveled by marked outline on skin to outline from step 1.

Figure 7.1.3.1: Arm Extended Behind Test–Dynamic Movement Arm Extended Behind Test with model placed in horizontal slot

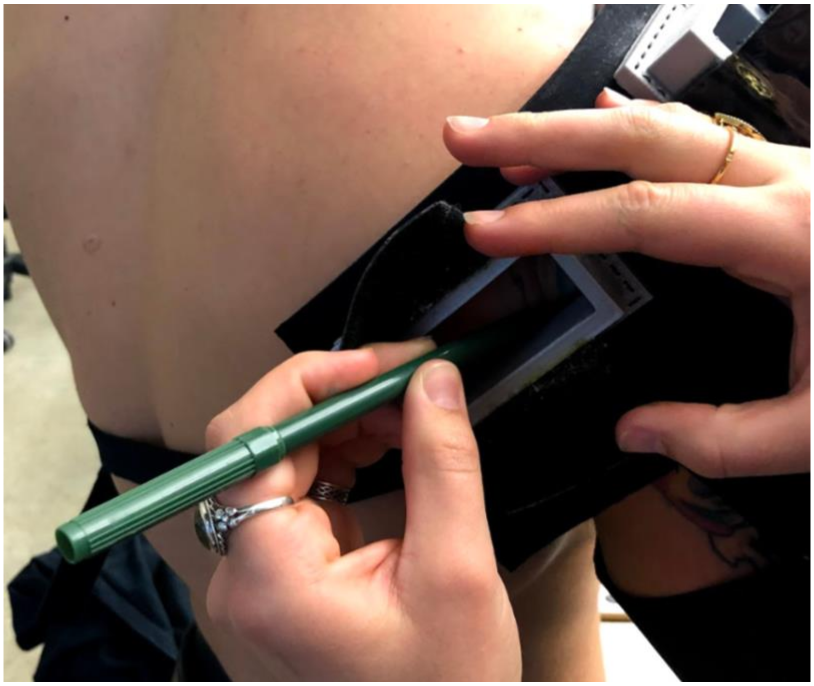


Figure 7.1.3.2: Dynamic Movement Test Setup–Initial position of the attachment ring was marked before testing

Figure 7.1.3.2: Dynamic Movement Test Results–Position of the attachment ring was marked in a different color after every test and displacement was measured

7.2 Verification and Validation

All angle displacements tests (structural and dynamic) resulted in an angle deflection of zero from datum. The statistical power for the Instron was 0.99, 0.842 for dynamic movement testing, and 1 for the initial structural testing.

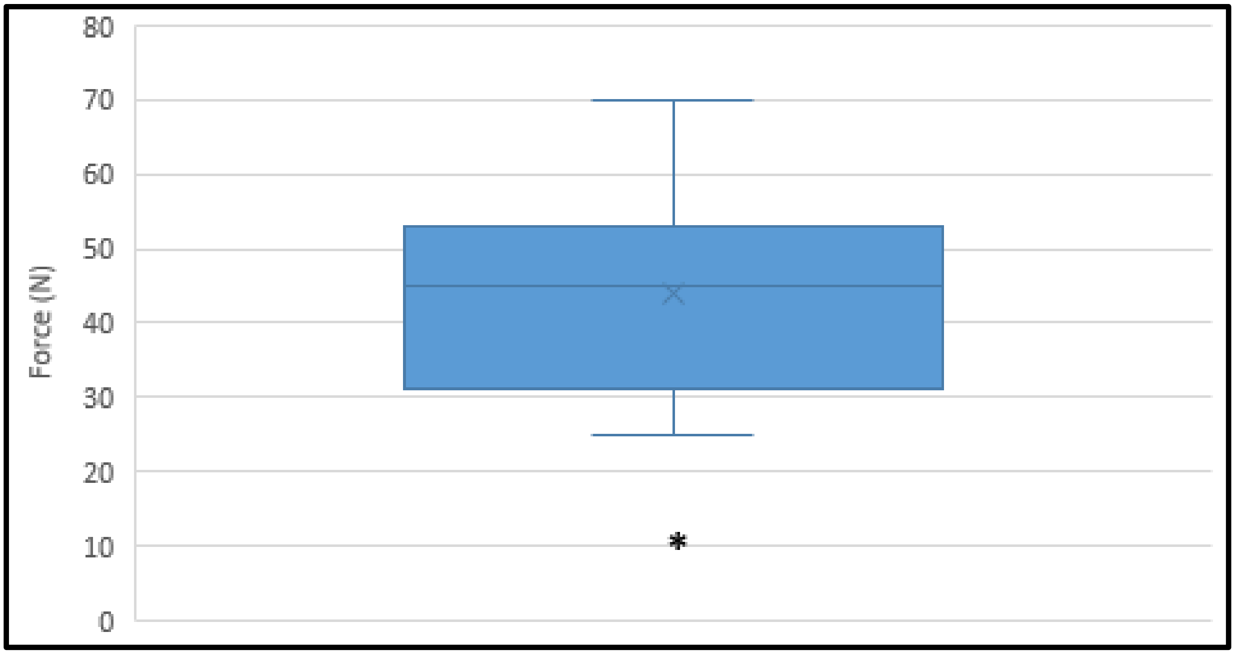
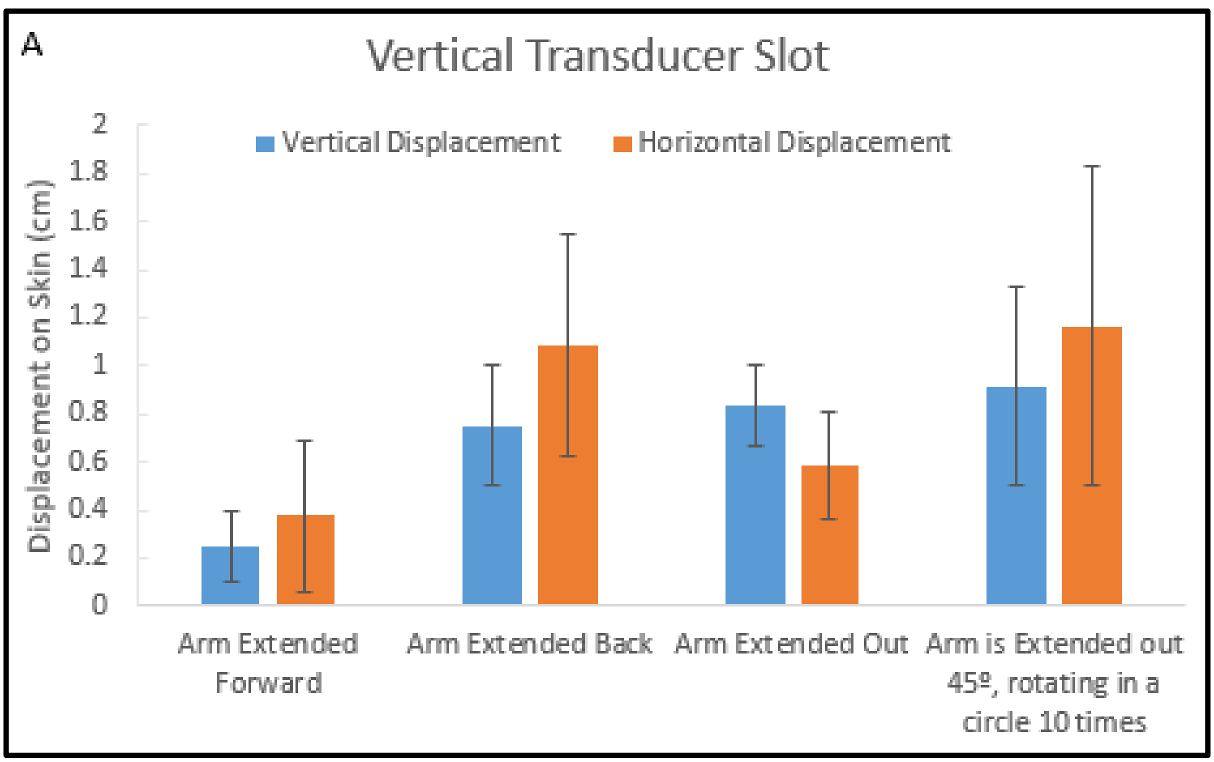


Figure 7.2.1: Instron Displacement. Initial vertical displacement over 12 trials. * represents the engineering specification needed.



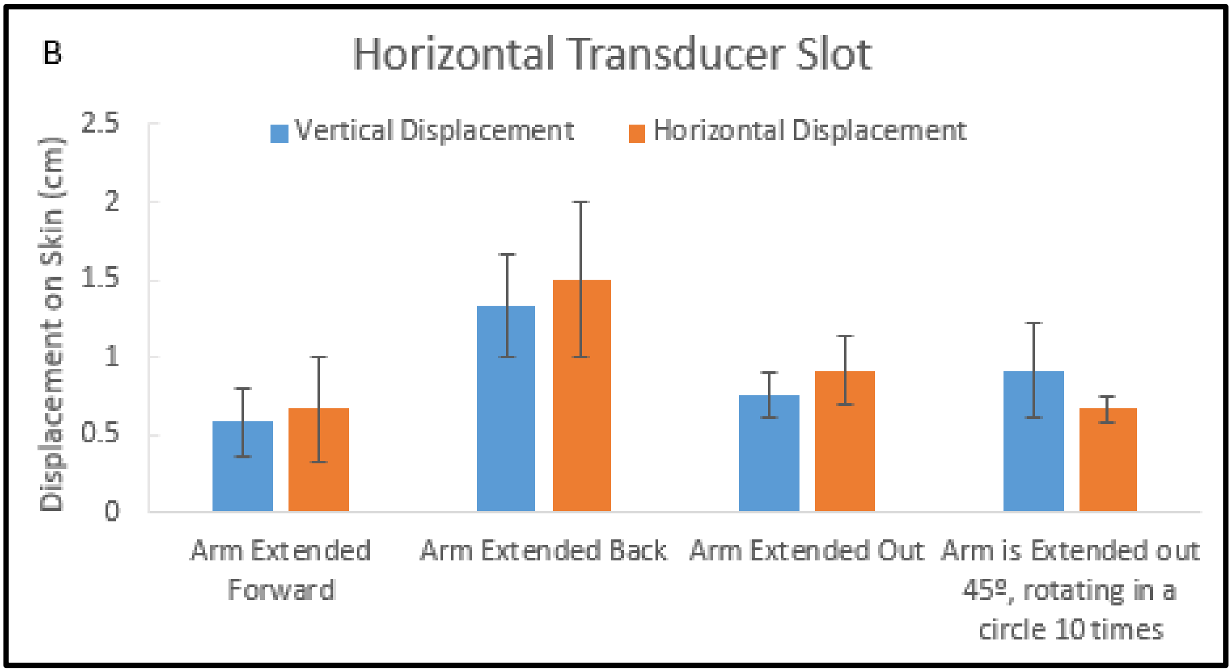


Figure 7.2.2: Transducer Displacement on Skin vs. Dynamic Movement. A: Vertical and horizontal displacement measured after dynamic movement performed on vertical slot of adapter. B: Vertical and horizontal displacement measured after dynamic movement performed on horizontal slot of adapter.

8.0 Conclusions and Recommendations

8.1 Recommendations

In the future, we would recommend groups make the device compatible with the *ButterflyiQ* Transducer. Unfortunately, since the device is not on the market yet, we were not able to design the attachment around it. We would also recommend that the next group get rid of the blood pressure cuff. Although it does provide some additional support, it is not necessary for the current specifications. Currently, our device is only compatible with the shoulder so we would also recommend that future groups make it compatible with different areas of the body. Lastly, we would recommend that the next group curve the attachment rings in order to perfectly fit the transducer. This would reduce the amount of displacement for Dynamic Movement Testing.

8.2 Conclusions

In conclusion, our design works well but could be improved. It meets all of the current specifications but can only be used in specific applications. The device works for ultrasounds performed on the shoulder with a model transducer similar to the Butterfly IQ.

9.0 Acknowledgments

Thank you to our sponsor Allison Sloben for her support through our project. We are also grateful for the guidance given by our professors Dr. Michael Whitt and Dr. Christopher Heylman.

10.0 Appendices

10.1 Appendix A: References

1. OrthoInfo. (2018). Rotator Cuff Tears. Retrieved from OrthoInfo.
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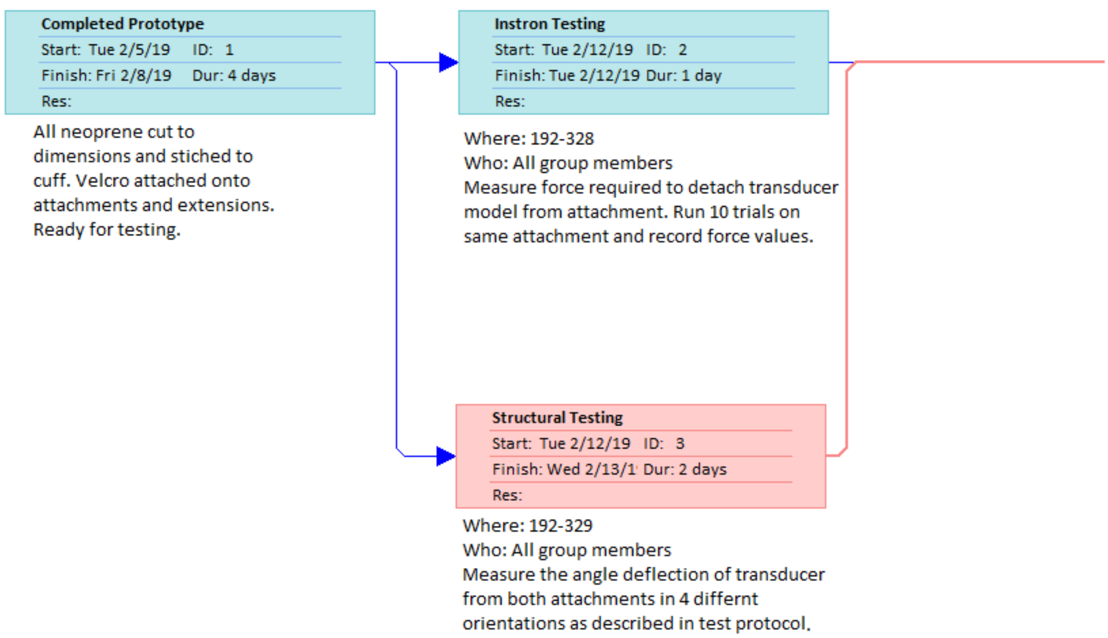
11. Douglas Miller, e. a. (2012). Overview of Therapeutic Ultrasound Applications and Safety Considerations. Ultrasound Medicine, 623-634.

10.2 Appendix B: Project Plan (PERT Chart)



Dynamic Movement Testing
Start: Thu 2/14/19 ID: 4
Finish: Fri 2/15/19 Dur: 2 days
Res:

Where: 192-329
Who: All group members
Perform 4 dynamic movements as described in protocol and measure angle deflections of model relative to attachment. Measure deflection of attachment on skin. Perform on dominant arm of all group members

Validation
Start: Mon 2/18/19 ID: 5
Finish: Fri 2/22/19 Dur: 5 days
Res:

1. Confirm that the force to pull out transducer is 10N +/- 1N.
2. Confirm that the angle of deflection for all trials is less than 5°.
3. Confirm that displacement on surface for all trials is less than 0.25".

10.3 Appendix C: CAD Drawings

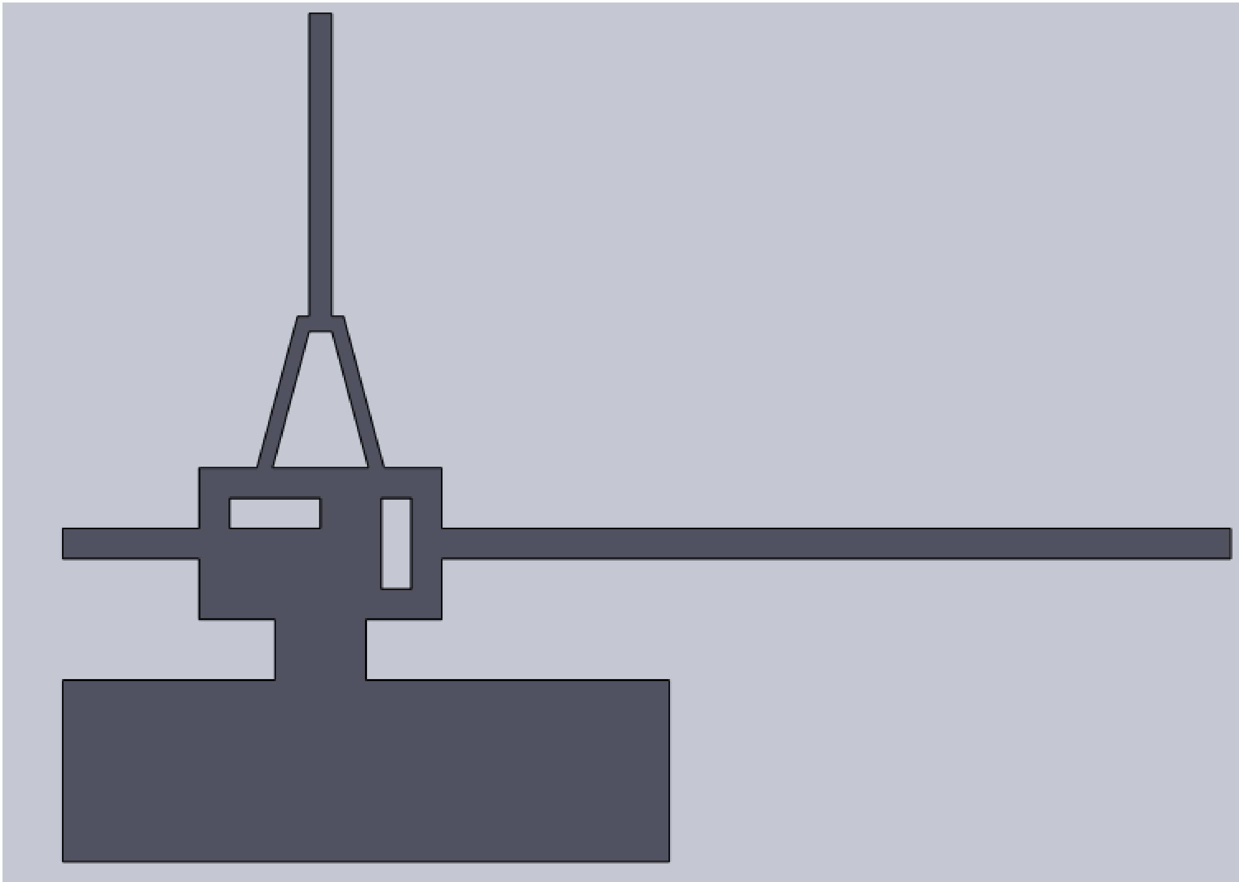


Figure 10.3.1: SolidWorks model of device

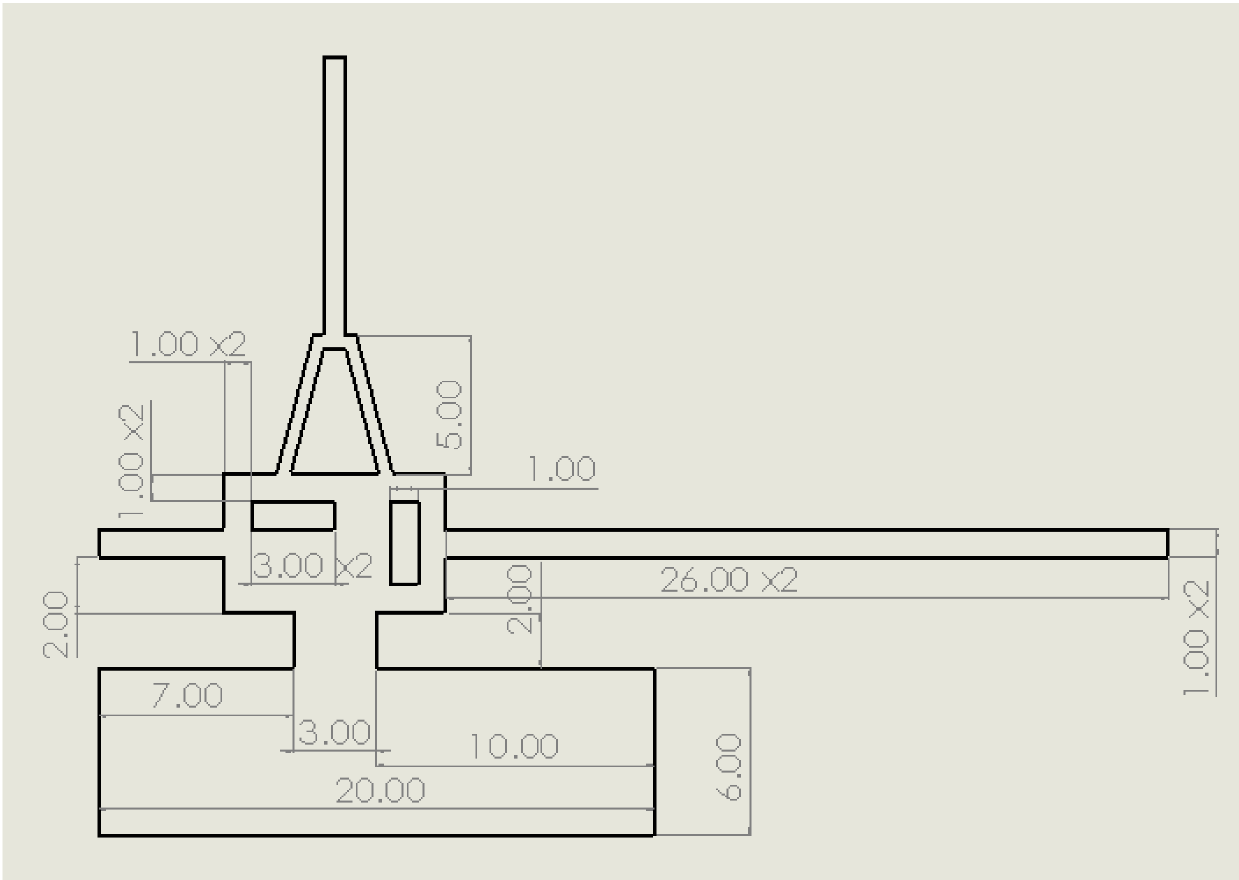


Figure 10.3.2: SolidWorks drawing of device

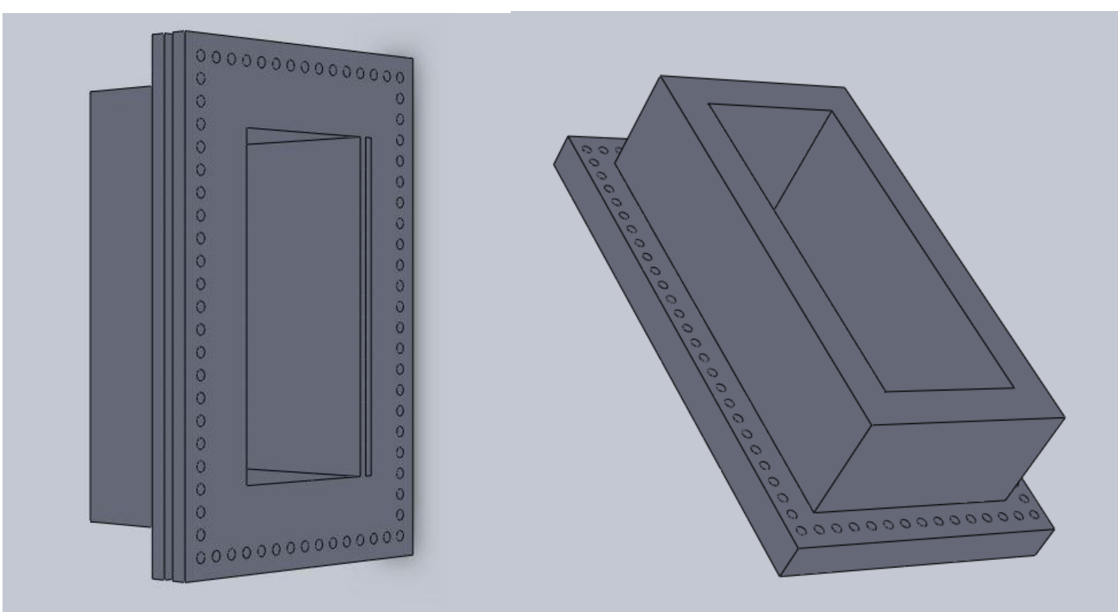


Figure 10.3.3: SolidWorks models of the 3D printed attachment rings

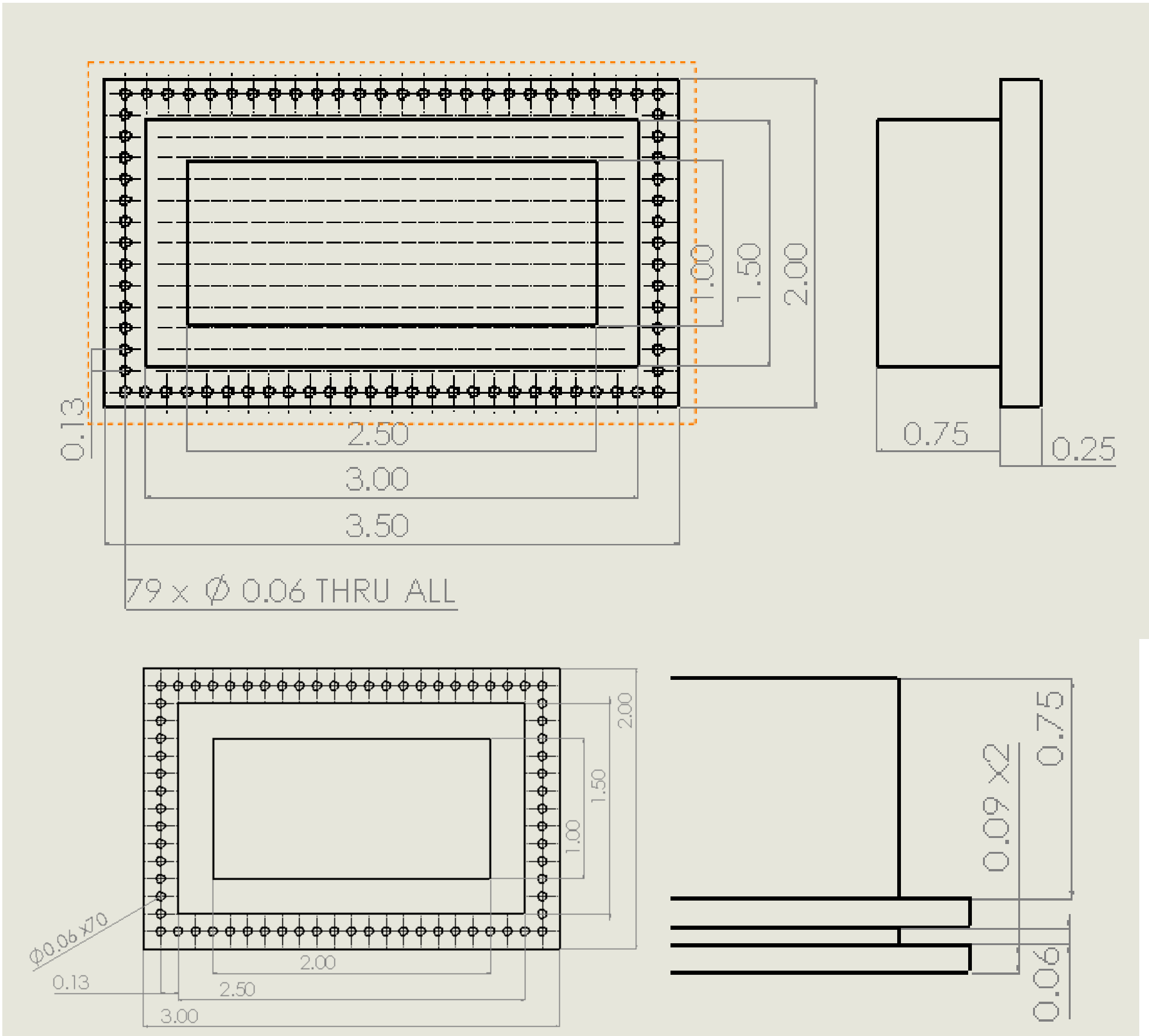


Figure 10.3.4: SolidWorks detailed drawings of the 3D printed attachment rings

10.4 Appendix D: FMEA, Hazard & Risk Assessment

10.4.1 FMEA

Table 10.4.1.1: FMEA

Component Name	Possible Failure Mode	Type	Cause of Failure	OCC	DET	SEV	RPN
Velcro	Unstrap/loosen	Raw Material	Velcro not strong enough	4	1	1	4
Air pump	Over pump	Sub Assembly	Increase in moisture	2	2	4	16
Air pump	Under pump	Sub Assembly	Increase in moisture	2	2	1	4
Neoprene	Could tear	Raw Material	High shear stress	1	3	1	3
Transducer Probe	Damaged or weak crystals	Sub Assembly	Probe was dropped on the floor	3	3	3	27
Transducer Probe	Cut or broken wire	Sub Assembly	Exposure to pressure over extended period	3	1	2	6
Transducer Probe	Defect in transducer probe	Sub Assembly	Cut by a sharp object such as a scalpel or wire	2	1	3	6
Central Processing Unit	Does not send waves correctly	Sub-Assembly	Excessive heat inside CPU	1	4	5	20
Central Processing Unit	Does not receive waves correctly	Sub-Assembly	Excessive heat inside CPU	2	3	3	18
Display	Cracks	Sub-Assembly	Device was dropped	3	1	3	9
Disk Storage Device	Does not save images	Sub Assembly	Excessive heat	1	2	3	6

Component Name	Possible Failure Mode	Cause of Failure	Effect of Failure on System	Failure Improvement Alternative Actions (actions to fix the problem…)
Velcro	Unstrap/ loosen	Velcro not strong enough	Device falls off or becomes loose	increase number of straps

Air pump	Over pump	Increase in moisture	Overtighten or explode	read moisture in room before using
Air pump	Under pump	Increase in moisture	Comes loose	read moisture in room before using
Neoprene	Could tear	High shear stress	Device would not inflate	Do not apply high shear stress to device
Transducer Probe	Damaged or weak crystals	Probe was dropped on the floor	Does send or receive ultrasound waves correctly	Handle transducer with care
Transducer Probe	Cut or broken wire	Exposure to pressure over extended period	Noise introduced to images	Handle transducer with care
Transducer Probe	Defect in transducer probe	Cut by a sharp object such as a scalpel or wire	Noise introduced to images	Handle transducer with care
Central Processing Unit	Does not send waves correctly	Excessive heat inside CPU	Patient burned from high energy waves	Develop attachment that turns device off when a certain temperature is reached
Central Processing Unit	Does not receive waves correctly	Excessive heat inside CPU	Image not reconstructed correctly	Develop attachment that turns device off when a certain temperature is reached
Display	Cracks	Device was dropped	Cannot read images or device settings	Handle transducer with care
Disk Storage Device	Does not save images	Excessive heat	Cannot read images	Install backup disk in case main disk stops working

10.4.2 Hazard & Risk Assessment

- Risks and Hazards:
  - Prolonged exposure to ultrasound waves can result in heat buildup in tissue, thus causing burns and tissue damage of patient and us while testing device
  - Over-tightening of cuff could cause restricted blood flow
  - Previously damaged rotator cuff could be irritated more if transducer is pressing in the wrong position
  - Possible dangers of building prototype in Bonderson

- Plans for decreasing risks and hazards:
  - Use large volumes of conductive gel (>22 ml/procedure)
  - Ultrasound does not exceed 10 minutes in one place on skin
  - Listen to patient; ask if they are in pain/discomfort
  - Follow all rules and regulations of Bonderson

10.5 Appendix E: Pugh Chart

Selection Criteria	Richmar AutoSound Hands-Free Ultrasound	Concept 1	Concept 2	Concept 3
Easy to take on and off	Datum	-	+	+
Stable during movement		0	+	+

Produces accurate images		+	+	+
Comfortable		0	0	0
Hands-free		+	+	+
Reasonably priced		0	+	+
Attaches to shoulder		+	-	+
Total # of "+" signs	N/A	3	5	6
Total # of "-" signs	N/A	2	1	0

10.6 Appendix F: Vendor Information, Specifications, and Data Sheets

Table 10.6.1: Raw Instron Data for Initial Displacement

Run	Displacement Force (N)
1	35
2	50
3	59

4	49
5	30
6	70
7	25
8	54
9	44
10	46
11	28
12	39

Table 10.6.2: Raw Data for Dynamic Testing

Displace-ment (cm)	Vertical				Horizontal			
	Arm Extended Forward	Arm Extended Back	Arm Extended Out	Arm Rotating	Arm Extended Forward	Arm Extended Back	Arm Extended Out	Arm Rotating
Christina Vertical	0.5	1	1	1.75	1	2	0.5	0.75
Harsh Vertical	0.25	1	0.5	0.5	0.5	1	1	1.5

Glenn Vertical	0	0.25	1	0.5	0.25	1	0.75	0.5
Christian Horizontal	0	0.5	0.5	0.5	1	2	1	0.75
Harsh Horizontal	1	2	1	2.5	0	0.5	0.5	0.5
Glenn Horizontal	0.125	0.75	0.25	0.5	1	2	1.25	0.75

10.7 Appendix G: Budget

Table 10.7.1: Bill of Materials

Material/Quantity	**Supplier**	**Cost**
Sphygmomanometer (2)	Amazon	$20
Velcro Packet (3)	Ace Hardware	$10

Wetsuit Neoprene 12x12 in (1)	Fetsy	$13
Liquid Electrical Tape (1)	Ace Hardware	$4
Industrial Thread Spool (1)	Beverly’s	$5
Industrial Sewing Needle Pack (1)	Beverly’s	$9
Plastic Epoxy (1)	Ace Hardware	$6
File (1)	Ace Hardware	$5
Protractor (1)	Ace Hardware	$5
Wire (1)	Ace Hardware	$2
Elastic Cord 54 inches (1)	Ace Hardware	$3
Ring for attaching cord (1)	Ace Hardware	$1
Total Cost	**$83**	